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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,972	02/28/2002	Ken-ichi Kosuna	1617.22B	3682
24040	7590	09/22/2004	EXAMINER	
MASON LAW, PL 17757 US HWY 19 N. CLEARWATER, FL 33764			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/045,972

Applicant(s)

KOSUNA, KEN-ICHI

Examiner

Susan D. Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed June 23, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1-21 are pending.
3. In applicant's response, applicant has pointed out the clerical error that has resulted in the entry of an incorrect response date for the previous response. The date has incorrectly been entered as 8/18/03 while the correct date for this response is 4/14/03. The examiner has requested correction of this clerical error but does not have the access to change this date herself.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 3-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the disease states claimed, does not reasonably provide enablement for "activating a brain function" to treat these diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative

skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Applicant's specification shows that the claimed composition has the ability to improve memory, inhibit lipid peroxide, treat hyperlipemia, lower triacylglycerol levels, and lower cholesterol levels. However, neither the specification nor the claims makes it clear how the composition is able to "active the brain" to bring about these effects. The specification also does not show how the brain itself is "activated." From the prior art, the claimed compounds appear to be antioxidants. It is known in the art that antioxidants typically exert a pharmaceutical effect at the site needed. For example, antioxidants inhibit lipid peroxidation by interacting directly with the lipids. No evidence in the art suggests that the brain is "activated" and somehow this reduces lipid peroxidation. Since it is unclear what functions in the brain are "activated" and how this activation leads to the results claimed, this link between disease treatment and brain activation is not considered to be enabled. Because this claimed link is unclear, a person of ordinary skill in the art would be forced to experiment unduly to determine if the composition functions by "activating" a portion of the brain.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1 and 21 are indefinite because the phrase "polymers having 4 to 9 monomer units having a molecular weight of from about 1,000 to about 10,000..." makes it unclear if the

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monomer unit has the specified molecular weight or if the polymer itself has the specified molecular weight.

6. Claims 3-14 are indefinite because the link between the “brain’s activity” and the treatment of the specified conditions is unclear. Applicant’s specification shows that the claimed composition has the ability to improve memory, inhibit lipid peroxide, treat hyperlipemia, lower triacylglycerol levels, and lower cholesterol levels. However, neither the specification nor the claims makes it clear how the composition is able to “active the brain” to bring about these effects. The specification also does not show how the brain itself is “activated.” Since it is unclear what functions in the brain are “activated” and how this activation leads to the results claimed, this link between disease treatment and brain activation is considered indefinite.

7. Claims 16 and 21 are indefinite because they state that R is both a dash OH **and** a wedge OH. Clearly, the OH bond cannot be both types at the same time. This same error is repeated in defining R’.

Claim Rejections - 35 USC § 102

8. Claims 1-20 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/36497 for the reasons set forth in the previous Office action.

All of applicant’s arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach the claimed invention because the reference does not have the same ratio of catechin to epicatechin claimed by applicant. Firstly, the ratio of catechin to epicatechin is only a limitation found in claims 16 and its dependents, claims 1-19. Thus, regarding claims 1-15 and 20, this argument is not

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persuasive because applicant is arguing limitations that are not in the claims. Secondly, WO '497 teaches structures that can meet applicant's claimed catechin to epicatechin ratios. The structures taught by WO '497 can be either catechin or epicatechin in a variety of ratios. These are all encompassed by the structural descriptions found on page 4 and other places throughout the reference. Therefore, WO '497 encompasses what is claimed by applicant.

Applicant has amended claim 16 to recite that the composition "consists essentially of" the claimed polymer. Regarding, the use of the transitional phrase "consisting essentially of," MPEP section 2111.03 states:

the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention... If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.

Applicant has not shown that the additional compounds taught by WO '497 would affect the basic and novel characteristics of the composition. Thus, WO '497 is still considered to teach claims 1-20.

Claim Rejections - 35 USC § 103

9. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/36497 in view of US Pat. No. 5,232,942 for the reasons set forth in the previous Office action. In the previous Office action, the statement of the basis of rejection inadvertently did not refer to WO 97/36497. However, WO 97/36497 was discussed in the body of the rejection, clearly showing that the rejection was based on this reference. Applicant has argued the rejection as such.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the combination of the references would not yield a reasonable expectation of success because US '942 is drawn to a low molecular weight compound while the invention is drawn to a high molecular weight compound. However, both WO '497 and US '492 are drawn to pharmaceutical compositions that are antioxidants. Antioxidants have the same mechanisms of action. This mechanism of action gives these compounds their common designation as "antioxidants." Therefore, since the mechanism of action is the same between the antioxidant of US '492 and WO '497, a person of ordinary skill in the art would reasonably expect that the antioxidants of WO '497 could be used to improve memory as taught by US '492.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Susan D. Coe, Examiner
September 16, 2004